

**AMENDMENT AND RESPONSE TO OFFICE ACTION**

**Remarks**

**Amendments to the Claims**

Claim 8 was amended to recast the claim as a method of treatment claim. Basis for the amendment is found in the specification as originally filed, for example on page 8, lines 10-15 and page 14, lines 18-22. New claim 9 was added to specifically identify the types of skin diseases or conditions to be treated. Basis for claim 9 is found in originally filed claim 8 as well as page 8, lines 10-15. No new matter is introduced by these amendments.

**Rejection of Claim 8 Under 35 U.S.C. §§ 101 and 112, second paragraph**

Claim 8 was rejected under 35 U.S.C. § 112, second paragraph as indefinite. Claim 8 was also rejected under 35 U.S.C. § 101 as being an improper process. Applicants have amended claim 8 to recast the claim as a method of treatment claim. In view of this amendment, the rejections are moot.

**Priority**

Applicants enclosed a certified copy of the priority document GB 0401634.1

**Rejection Under 35 U.S.C. § 103**

Claims 1-7 were rejected under 35 U.S.C. § 103(a) as being unpatentable over RU 2180213 (“RU ‘213”) or RU 2185814 (“RU ‘814”) in view of Albrecht et al. (US Patent Publication No. 2006/0121807). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

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**Legal Standard**

The starting point for an obviousness determination must be the Supreme Court's decision in *KSR v. Teleflex*, 550 U.S. 398 (2007), which refocuses the determination of whether a claimed invention is obvious back to the process the Court had defined in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966). There, the Court had held that the obviousness determination should address four factors, all of which must be considered, though not in any prescribed order: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) any secondary considerations suggesting nonobviousness, such as commercial success, failure of others, and long felt but unmet need. *Id.* The Court cautioned that the fact finder should be careful about reading the teachings of the invention at issue into the prior art, to avoid applying inappropriate hindsight, *ex post* reasoning. *Id. at 36.*

Even where the prior art suggests or motivates an inventor to develop the composition or process at issue, the Federal Circuit continues to recognize that there is a critical question under 35 U.S.C. § 103 as to whether the combined teachings of the prior art "would have given rise to a reasonable expectation of success" in achieving what is claimed. *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007), *cert. denied*, 128 S. Ct. 1655 (US 2008). There, the inventors merely used routine research methods to prove what was already believed to be the case and had not made a patentable invention. *Id. at 1363-64*. However, the court noted that a different case is presented if all the prior art suggested was to explore a general

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approach and gave only general guidance as to the particular form of the claimed invention or how to achieve it. *Id.* at 1364-65 (citing *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988), and *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1166-67 (Fed. Cir. 2006), as continuing to provide useful guidance in determining whether the expectation of success from a line of inquiry found in prior art is so great as to make a resulting invention obvious).

The Examiner's attention is directed to the recent Court of Appeals for the Federal Circuit decision, *In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009). The following quotes from this decision clarify when "obvious to try" is "obviousness", and when it is not.

"The Supreme Court's admonition against a formalistic approach to obviousness in this context actually resurrects this court's own wisdom in In re O'Farrell, which predates the Deuel decision by some seven years. This court in O'Farrell cautioned that "obvious to try" is an incantation whose meaning is often misunderstood:

It is true that this court and its predecessors have repeatedly emphasized that "obvious to try" is not the standard under § 103. However, the meaning of this maxim is sometimes lost. Any invention that would in fact have been obvious under § 103 would also have been, in a sense, obvious to try. The question is: when is an invention that was obvious to try nevertheless nonobvious?

In re O'Farrell, 853 F.2d 894, 903 (Fed. Cir. 1988). To differentiate between proper and improper applications of "obvious to try," this court outlined two

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classes of situations where “obvious to try” is erroneously equated with obviousness under § 103.

In the first class of cases, what would have been “obvious to try” would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful. Id. In such circumstances, where a defendant merely throws metaphorical darts at a board filled with combinatorial prior art possibilities, courts should not succumb to hindsight claims of obviousness. The inverse of this proposition is succinctly encapsulated by the Supreme Court’s statement in KSR that where a skilled artisan merely pursues “known options” from a “finite number of identified, predictable solutions,” obviousness under § 103 arises. 550 U.S. at 421.

The second class of O’Farrell’s impermissible “obvious to try” situations occurs where what was “obvious to try” was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it. 853 F.2d at 903. Again, KSR affirmed the logical inverse of this statement by stating that § 103 bars patentability unless “the improvement is more than the predictable use of prior art elements according to their established functions. “550 U.S. at 417”.

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**Analysis**

**Claim 1**

Claim 1 defines a soap containing glycerine and sapropel. It appears that the Examiner considers glycerine to be a fatty acid. This is incorrect. Glycerine is not a fatty acid. Applicant encloses the definitions of “glycerine” and “fatty acid” from Hawley’s Condensed Chemical Dictionary, 14<sup>th</sup> Ed. (2001) pages 484 and 539 for the Examiner’s consideration. Glycerine is also known as glycerol or 1,2,3-prppanetriol. Hawley’s defines a fatty acid as a chain of alkyl groups with a terminal **carboxylic acid**. Glycerine is an alcohol, not a carboxylic acid.

**The Combination of References Fails to Disclose or Suggest Each Element of the Claims**

RU ‘213 discloses cosmetic compositions containing sapropels. RU ‘814 discloses cosmetic agents containing sapropetic curative silt. Albrecht et al. discloses substrates impregnated with fatty acids. Albrecht et al. mentions in passing that soaps can be produced by saponification of fatty acids. None of the references either alone or in combination disclose or suggest a soap containing sapropel and glycerine. Therefore, claims 1-9 are non-obvious over the combination of the cited references, and the rejection should be withdrawn.

Applicant also advises the Examiner that the corresponding European patent application with similar claims granted as EP 1 713 438 B1(copy enclosed).

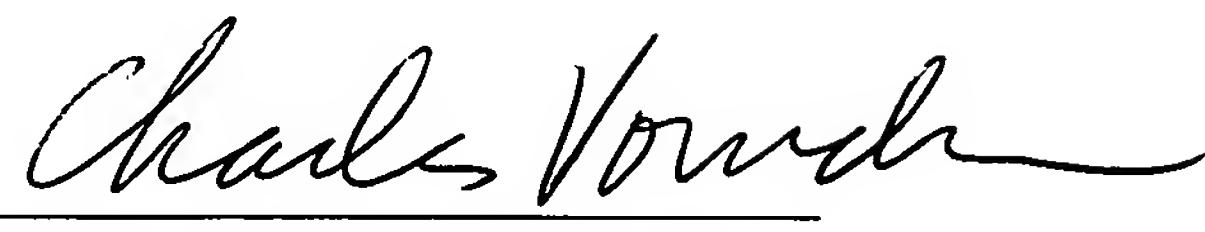
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Allowance of claims 1-9 is respectfully solicited.

Respectfully submitted,

  
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